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(71) Applicant *(for all designated States except US)*: **CARMEL PHARMA AB** [SE/SE]; Box 5352, S-402 28 Göteborg (SE).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **ÅKERLUND, Roger** [SE/SE]; Byalagsgatan 12D, S-418 74 Göteborg (SE). **ANDREASSON, Kjell** [SE/SE]; Rödtungegatan 10B, S-426 58 Västra Frölunda (SE).

(74) Agent: **STRÖM & GULLIKSSON IP AB**; Sjöporten 4, S-417 64 GöTEBORG (SE).

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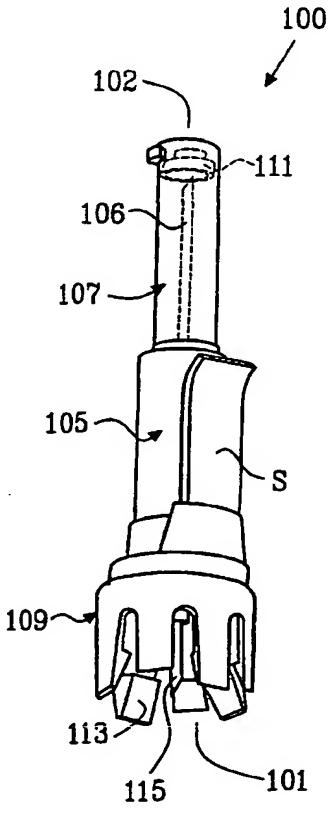
(54) Title: METHOD AND DEVICE FOR FLUID TRANSFER IN AN INFUSION SYSTEM



(57) Abstract: A fluid transfer device (100) for use in an infusion system, which device exhibits a first end (101) and a second end (102) for coupling to an injection port of the infusion system. The device (100) further includes at least a fist member (105), a hollow needle (106) attached to the first member, and a second member (107) which is telescopically displaceable in relation to the first member (105) and allows the hollow needle (106) to penetrate a flexible barrier member sealing the injection port in order to create a fluid passage into the infusion system. The first end (101) exhibits a connecting portion (109) for attachment to a drug bottle containing a fixed dose of medical substance, and the second end (102) exhibits a flexible membrane (111) intended to be pressed against the flexible barrier member with a pressure sufficient to create a double-membrane sealing around the hollow needle (106).

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Title

Method and device for fluid transfer in an infusion system.

Technical field

The present invention relates to a fluid transfer device for use in an infusion system, which device exhibits a first end, a second end opposite to the first end, the second end being designed and arranged for coupling to an injection port of the infusion system, wherein the fluid transfer device includes at least a first member, a hollow needle attached to the first member, and a second member which is telescopically displaceable in relation to the first member in a way allowing the hollow needle to penetrate a flexible barrier member sealing the injection port in order to create a fluid passage from the first end via the injection port into the infusion system. The present invention also relates to a drug bottle for use with the fluid transfer device, and a method for fluid transfer which utilises the fluid transfer device.

Background of the invention

A serious problem in connection with drug preparation, drug administration and other similar handling is the risk that medical and pharmacological staff are exposed to drugs or solvents which might escape into the ambient air. This problem is particularly serious when cytotoxins, antiviral drugs, antibiotics and radiopharmaceuticals are concerned.

For this reason, there has been a need of safer systems for handling and administrating drugs and other medical substances.

Accordingly, U.S. Patent No. 4,564,054 (Gustavsson) discloses a fluid transfer device for transferring a substance from one vessel to another vessel while avoiding leakage of liquid and gas contaminants. The disclosed device comprises a first member designed as a hollow sleeve and having a piercing member provided with a passageway. The piercing member is attached to the first member which has a first barrier member at one end just opposite the tip of the piercing member. Thereby, the piercing member can be passed and retracted through the first barrier member which seals one end of the first member. The fluid transfer device further comprises a

second member which is attached to or attachable to one of the vessels or to means arranged to communicate therewith. The second member has a second barrier member, and mating connection means arranged on the first and second members for providing a releasable locking of the members with respect to each other. The barrier members are liquid and gas-proof sealing members which seal tightly after penetration and retraction of the piercing member and prevent leakage of liquid as well as gas contaminants. In the connected position of the first and second members, the barrier members are located in such a way with respect to each other that the piercing member can be passed therethrough.

According to US 4,564,054, the above-mentioned piercing member is a needle arranged for puncturing the first and the second barrier members, wherein the end opposite to the one end of the first member has means for sealingly receiving or being permanently attached to an injection syringe or the like for withdrawing and/or adding substance to the vessel attached to the second member. When attached to the first member, the injection syringe or the like communicates with the passageway of the needle, so that in the retracted position the needle is hermetically enclosed in the first member having the injection syringe or the like connected thereto.

The international patent publication No. WO 99/27886 (Fowles et. al) discloses a connector device intended for establishing fluid communication between a first container and a second container. The connector device comprises a first sleeve member having a first and a second end, wherein the first sleeve member has a first attaching member at the first end which is adapted to attach to the first container. The connector device further comprises a second sleeve member which has a first end and a second end. Thereby, the second sleeve member is associated to the first sleeve member and movable with respect thereto from an inactivated position to an activated position, wherein the second sleeve member has a second attaching member at the second end adapted to attach the second sleeve member to the second container. According to WO 99/27886, the connector device further comprises a first and second piercing member projecting from one of the first and second sleeve members for providing a fluid flow path from the first container to the second container, and means for independently hermetically sealing the first and second members.

Furthermore, U.S. Patent No. 6,258,078 B1 discloses a luer connector which facilitates connection of a hypodermic syringe to the vial, comprising a luer

connectable to a syringe and which extends to a sharpened end capable of being driven through a puncturable vial closure to thereby puncture the closure, a luer support mountable on a vial, and which initially supports the luer in a first position in which the sharpened end of the conduit is pointed towards the closure, and a luer driver such that movement of the driver relative to the support causes the luer to be driven so that the sharpened end punctures the closure and enters the vial.

When performing infusion, it is often necessary to inject a drug or other medical substance into the infusion fluid inside an infusion bag or other infusion fluid container. This is often done by means of penetrating a septum or other fluid barrier of an injection port on the infusion bag or on the infusion fluid line with a needle of a syringe filled with the medical fluid in question.

However, it has been found that the use of a regular syringe or other devices according to prior art, when injecting hazardous substances such as cytotoxins into an infusion bag or infusion fluid line, might cause pollution of the working environment because of leakage, something which of course is unacceptable. For this reason, there is a need of an improved device which eliminates the risk that potentially health-hazardous substances escape into the ambient air or working environment when injecting a drug or another medical substance into an infusion system, and which device safely can be disconnected from the infusion system after having performed the injection.

Summary of the invention

Accordingly, a first object of the present invention is to provide a simple, reliable and safe fluid transfer device for use when injecting a medical substance into an infusion system, which device eliminates the risk that hazardous substances escape into the environment.

In accordance with claim 1, this first object is achieved by means of fluid transfer device exhibiting a first end and a second end opposite to the first end, wherein the second end is designed and arranged for coupling to an injection port of the infusion system. The fluid transfer device includes at least a first member, a hollow needle attached to the first member, and a second member which is telescopically displaceable in relation to the first member in a way allowing the hollow needle to penetrate a flexible barrier member sealing the injection port in order to create a fluid passage from the first end via the injection port into the infusion system. The

first end exhibits a connecting portion for attachment to a drug bottle containing a fixed dose of a medical substance, wherein the second end exhibits a flexible membrane intended to be pressed against the flexible barrier member of the injection port with a pressure sufficient in order to create a double-membrane sealing around the hollow needle when creating the fluid passage into the infusion system.

A second object of the present invention is to provide a drug bottle for use with the fluid transfer device according to the invention.

In accordance with claim 18, this second object is achieved by means of a drug bottle which contains a fixed dose of a medical substance, and which is intended for attachment to the fluid transfer device according to the invention.

A third object of the present invention is to provide a method for fluid transfer in an infusion system which utilises the fluid transfer device according to the invention.

In accordance with claim 25, the method includes to use a fluid transfer device to inject a medical substance into the infusion system via an injection port sealed by a flexible barrier member. Thereby, the fluid transfer device includes at least a first member, a hollow needle attached to the first member, and a second member which is telescopically displaceable in relation to the first member. The method includes to provide the fluid transfer device having a first end, and a second, opposite end exhibiting a flexible membrane, to provide a drug bottle containing a fixed dose of the medical substance, to attach the first end to the drug bottle, and to couple the second end to the injection port while pressing the flexible membrane against the flexible barrier member with a pressure sufficient for creating a double-membrane sealing. The method further includes to create a fluid passage from the first end to the infusion system by means of telescopically displacing the first end in a direction towards the second end in order to get the hollow needle to penetrate the flexible membrane and the flexible barrier member while being surrounded by the double-membrane sealing, and to transfer the fixed dose from the drug bottle into the infusion system by means of creating and subsequently releasing a positive pressure inside the drug bottle.

Further objects of the present invention will become evident from the following description, and the features enabling these further objects to be achieved are listed in the dependent claims.

Brief description of drawings

In the following, the present invention will be described in greater detail with reference to the attached drawings, in which

Fig. 1 is a schematic illustration of a portion of an infusion system in which a fluid transfer device according to the present invention is utilised;

Fig. 2 is a schematic perspective view of a fluid transfer device according to a first, preferred embodiment of the invention;

Fig. 3 is an exploded view of the fluid transfer device in Fig. 2;

Fig. 4 shows the interior of the fluid transfer device in Fig. 2;

Fig. 5 is a schematic perspective view of a fluid transfer device according to a second embodiment of the invention;

Fig. 6 shows a drug bottle according to a first embodiment of the invention, intended for use with the fluid transfer device in Fig. 2;

Fig. 7 shows a drug bottle according to a second embodiment of the invention, intended for use with the fluid transfer device in Fig. 5;

Fig. 8 shows the drug bottle in Fig. 6 permanently attached to a separate connecting portion which exhibits a Luer-lock connector for attachment to the fluid transfer device in Fig. 5 by means of a Luer-lock coupling;

Fig. 9 shows the drug bottle in Fig. 6 permanently attached to a separate connecting portion of a fluid transfer device according to an alternative embodiment of the invention;

Fig. 10 is a schematic illustration of a portion of an infusion system in which a fluid transfer device according an alternative embodiment of the invention is utilised; and

Fig. 11 shows the fluid transfer device of Fig. 5 and the drug bottle of Fig. 7 when coupled to a spike device of an alternative infusion system.

Detailed description of preferred embodiments

In the following, a preferred embodiment and a number of alternative embodiments of a fluid transfer device according to the invention will be described in greater detail with reference to the attached Figs. 1 – 11.

The fluid transfer device 100; 200 according to the invention is intended for use in an infusion system and exhibits a first end 101; 201 and a second end 102; 202 opposite to the first end, wherein the second end 102; 202 is designed and arranged for coupling to an injection port 103; 203 of the infusion system 104; 204.

The fluid transfer device 100; 200 includes at least a first member 105; 205, a hollow needle 106; 206 attached to the first member, and a second member 107; 207 which is telescopically displaceable in relation to the first member 105; 205 in a way allowing the hollow needle 106; 206 to penetrate a flexible barrier member 108; 208 sealing the injection port 103; 203 in order to create a fluid passage from the first end 101; 201 via the injection port 103; 203 into the infusion system 104; 204.

According to the invention, the first end 101; 201 exhibits a connecting portion 109; 209; 309; 409 for attachment to a drug bottle 110; 210 containing a fixed dose D of a medical substance. The expression "fixed dose" should be understood as a predetermined quantity of the medical substance in question, which quantity has been adapted to the patient in question and which quantity is to be transferred in its entirety into the infusion system.

Furthermore, according to the invention, the second end 102; 202 exhibits a flexible membrane 111; 211 intended to be pressed against the flexible barrier member 108; 208 of the injection port 103; 203 with a pressure sufficient in order to create a double-membrane sealing 108, 111; 108, 211; 208, 211 around the hollow needle 106; 206 when creating the fluid passage into the infusion system 104; 204.

In a preferred embodiment of the fluid transfer device according to the invention, the flexible membrane 111; 211 is made of a polymer material exhibiting a yield point when subjected to the pressure, wherein the second end 102; 202 is designed and arranged for interacting with the injection port 103; 203 in order to increase the pressure above the yield point. This ensures that a leakage-proof sealing can be achieved. Even more advantageously, the flexible membrane 111; 211 and the

flexible barrier member 108; 208 are made of identical or similar materials which reach their yield points at the same pressure level.

Advantageously, the second end 102; 202 of the fluid transfer device is designed and arranged for creating the double-membrane sealing 108, 111; 108, 211 when the injection port 103 is provided on a flexible infusion bag 112 of the infusion system 104. Alternatively, the second end is designed and arranged for creating the double-membrane sealing when the injection port is provided on an infusion fluid line of the infusion system, or when the injection port has been connected to a separate spike device SP exhibiting the flexible barrier member 208. Preferably, the second end is designed and arranged for all these cases.

In the preferred embodiment, the second end 102; 202 is designed and arranged for creating a double-membrane bayonet coupling with the injection port 103. Double-membrane bayonet couplings are known *per se* from the above-discussed U.S. Patent No. 4,564,054.

In a first, preferred embodiment of the invention, as illustrated in Figs. 1-4 and 8, the connecting portion 109; 309 exhibits at least one locking member 113; 313 for grasping a bottle neck 114 of the drug bottle 110 in order to create a permanent attachment, wherein the connecting portion 109; 309 further exhibits a hollow piercing member 115 for penetrating a bottle cap 116 of the drug bottle 110 in order to extend the fluid passage into the drug bottle. This embodiment is particularly useful for drug bottles/vials of the type illustrated in fig. 6.

In the first embodiment of the invention, as illustrated in Fig. 4, the connecting portion 109 exhibits a hollow piercing member 115 for penetrating a bottle cap 116 of the drug bottle 110 (Fig. 6) in order to extend the fluid passage into the drug bottle. In this embodiment, as indicated in Fig. 4, neighbouring ends of the hollow piercing member 115 and the hollow needle 106 are designed and arranged in a way allowing fluid communication through the hollow piercing member 115 into the hollow needle 106.

In an alternative embodiment (not shown in the drawings), the connecting portion exhibits a hollow piercing member for penetrating a bottle cap of the drug bottle in order to extend the fluid passage into the drug bottle, wherein the hollow piercing member is constituted of a sharpened end of the hollow needle being exposed at the

first end of the fluid transfer device. Accordingly, the components 106 and 115 in the embodiment shown in Fig. 4 could be replaced by a single hollow needle with two sharpened opposite ends.

In a second embodiment of the fluid transfer device according to the invention, illustrated in Figs. 5 and 7, the connecting portion 209 exhibits a first coupling member 213 for engaging a second coupling member 217 provided on a bottle cap 216 of the drug bottle 210 in order to create the attachment by means of a Luer-lock coupling. Luer-lock couplings are well known *per se*, but for other uses.

In the second embodiment, the connecting portion 209 preferably exhibits a first coupling member 213 for attachment to a second coupling member 217 provided on a bottle cap 216 of the drug bottle 210, wherein a fluid barrier member 218 is provided in a duct 219 extending between an interior D of the drug bottle 210 and the second coupling member 217 and the fluid barrier member 218 can be ruptured by means of an external force in order to extend the fluid passage into the drug bottle 210. Accordingly, in the second embodiment, the breakable fluid barrier member 218 provides the function of the piercing member 115 penetrating the bottle cap 116 of the drug bottle in the first embodiment.

In the second embodiment, as illustrated in Figs. 5 and 7, the connecting portion 209 advantageously exhibits a first coupling member 213 for attachment to a second coupling member 217 which is permanently attached to the drug bottle 210 at least partly by means of an annular capsule member 220. However, it is also conceivable that the second coupling member is attached to the drug bottle in another suitable way.

In the second embodiment, the connecting portion preferably exhibits a female Luer-lock connector 221 for attachment to a male Luer-lock connector 222 provided on the drug bottle 210 or, alternatively, the connecting portion exhibits a male Luer-lock connector for attachment to a female Luer-lock connector provided on the drug bottle.

In the first, preferred embodiment of the fluid transfer device according to the invention, as illustrated in Figs. 2 – 4, the connecting portion is a separate component 109 which has been attached to the first member 105 before the permanent attachment to the drug bottle 110.

In a particularly advantageous embodiment, the connecting portion is an integrated part 209 of the first member 205, e.g. as illustrated in Figs. 5 and 7. Alternatively, components 105 and 109 in Fig. 3 could be replaced by a single component instead.

In another alternative embodiment, as illustrated by Figs 5 and 8 together. the connecting portion is a separate component 309 which exhibits a Luer-lock connector 323 for attachment to the first member 205 by means of a Luer-lock coupling 221, 323. This embodiment makes it possible to utilise the same type of fluid transfer device 200 with different drug bottles, e.g. the two types illustrated in Figs. 6 and 7.

In still another alternative embodiment, as illustrated in Figs 9 and 10 together, the connecting portion is a separate component 409 which exhibits a Luer-lock connector 423 for attachment to the first member by means of a Luer-lock coupling 221, 423. In this embodiment, the connecting portion further exhibits at least one locking member 413 for grasping a bottle neck of the drug bottle 110 in order to create a permanent attachment, and a hollow piercing member 415 for penetrating a bottle cap of the drug bottle 110 in order to extend the fluid passage into the drug bottle.

In the following, a preferred embodiment and a number of alternative embodiments of a drug bottle according to the invention will be described with particular reference to Figs. 6-9.

The drug bottle 110; 210 according to the invention contains a fixed dose D of a medical substance, wherein the drug bottle 110; 210 is intended for attachment to a fluid transfer device 100; 200 according to the invention.

In a first advantageous embodiment, illustrated in Fig. 6, the drug bottle 110 exhibits a bottle neck 114 intended to be grasped by at least one locking member 113 of the connecting portion 109 in order to create a permanent attachment. Preferably, as indicated in Figs. 8 and 9, the drug bottle 110 exhibits a bottle cap 116 intended to be pierced by a piercing member 115; 315 being part of the fluid transfer device according to the invention.

In a second, preferred embodiment of the drug bottle according to the invention, illustrated in Fig. 7, the drug bottle 210 is sealed by a bottle cap 216 exhibiting a

second coupling member 217 intended to be attached to a first coupling member 213 of the connecting portion 209.

In a particularly preferred embodiment, as illustrated in Fig. 7, the drug bottle 210 is sealed by a bottle cap 216 exhibiting a second coupling member 217, wherein a fluid barrier member 218 is provided in a duct 219 extending between an interior D of said drug bottle 210 and the second coupling member 214, which fluid barrier member 218 can be ruptured by means of an external force in order to open the duct 219. Breakable fluid barrier members are known *per se*, but for other uses, and can be designed in any suitable way and from any suitable material as long as the barrier is capable of performing the desired function.

As illustrated in Fig. 9, it is also conceivable with embodiments where the breakable fluid barrier member is replaced or assisted by a suitable clamping member C. The clamping member C further makes it possible to prevent undesired reflux of drug/infusion fluid into the drug bottle while this is connected to the infusion system. Such clamping members are known *per se*.

Advantageously, as illustrated in Fig. 7, the drug bottle 210 is sealed by a bottle cap 216 exhibiting a second coupling member 217 intended to be attached to a first coupling member 213 of the connecting portion 209, wherein the second coupling member 217 is permanently attached to the drug bottle 210 at least partly by means of an annular capsule member 220. This embodiment makes it possible to utilise fairly conventional machinery for attaching such a specially-designed bottle cap to a drug bottle or vial.

Most preferably, as illustrated in Fig. 7, the drug bottle 210 is sealed by a bottle cap 216 exhibiting a male Luer-lock connector 222 intended to be attached to a female Luer-lock connector 221 of said connecting portion 209. Alternatively, the drug bottle is sealed by a bottle cap exhibiting a female Luer-lock connector intended to be attached to a male Luer-lock connector of the connecting portion.

In the following, a preferred embodiment and a number of alternative embodiments of a method for fluid transfer in an infusion system according to the invention will be described in greater detail with reference to the attached Figs. 1 – 11.

The method includes to use a fluid transfer device 100; 200 to inject a medical substance into the infusion system 104 via an injection port 103 sealed by a flexible barrier member 108. The fluid transfer device includes at least a first member 105; 205, a hollow needle 106; 206 attached to the first member, and a second member 107; 207 which is telescopically displaceable in relation to the first member 105; 205.

According to the invention, the method includes to provide the fluid transfer device 100; 200 having a first end 101; 201, and a second, opposite end 102; 202 exhibiting a flexible membrane 111; 211, to provide a drug bottle 110; 210 containing a fixed dose D of the medical substance, to attach the first end 101; 201 to the drug bottle 110; 210, and to couple the second end 101; 201 to the injection port 103 while pressing the flexible membrane 111; 211 against the flexible barrier member 108 with a pressure sufficient for creating a double-membrane sealing 108, 111; 108, 211.

Furthermore, according to the invention, the method includes to create a fluid passage from the first end 101; 201 to the infusion system by means of telescopically displacing the first end 101; 201 in a direction towards the second end 102; 202 in order to get the hollow needle 106; 206 to penetrate the flexible membrane 111; 211 and the flexible barrier member 108 while being surrounded by the double-membrane sealing 108, 111; 108, 211, and to transfer the fixed dose D from the drug bottle 110; 210 into the infusion system 104 by means of creating and subsequently releasing a positive pressure inside the drug bottle 110; 210.

In a preferred embodiment, the method further includes to increase the pressure above a yield point of a polymer material constituting the flexible membrane 111; 211.

Advantageously, the injection port 103 is provided on a flexible infusion bag 112 of the infusion system 104. Alternatively, the injection port is provided on an infusion fluid line of the infusion system.

In the preferred embodiment of the method, the second end 102; 202 creates a double-membrane bayonet coupling with the injection port 103.

In a first embodiment according to the invention, the method further includes to penetrate a bottle cap 116 of the drug bottle 110 by means of a hollow piercing

member 115; 315 in order to extend the fluid passage into the drug bottle, and to grasp a bottle neck 114 of the drug bottle 110 by means of at least one locking member 113 of the fluid transfer device 100 in order to create a permanent attachment.

In an alternative embodiment of the method according to the invention, as illustrated by Figs. 5 and 7, the attachment is created by means of a Luer-lock coupling 221; 222.

In another embodiment of the method according to the invention, as illustrated in Fig. 7, a fluid barrier member 218 blocking a duct 219 extending through the bottle cap 216 is ruptured by means of an external force when extending the fluid passage into the drug bottle 210.

In an alternative embodiment of the method, illustrated in Fig. 9, a clamping member C is utilised for applying an external pressure on a duct 419 extending through the bottle cap in order to block the fluid passage into the drug bottle. The use of such clamping members makes it possible to connect different components of an infusion system to each other without any risk of hazardous leakage to the environment also in embodiments where there are no breakable fluid barrier members or the like sealing the fluid containers of the infusion system.

In still another alternative embodiment, illustrated in Fig. 11, the flexible membrane 211 of the second end is pressed against a flexible barrier member 208 of a spike device SP connected to the infusion system 204 before transferring the fixed dose from the drug bottle 210 into the infusion system 204. As illustrated in Fig. 11, a clamping member C advantageously is provided in order to ensure that the drug can be transferred from the drug bottle 210 into infusion fluid container 212 in order to be mixed with the infusion fluid before initiating infusion through the infusion line L.

In another advantageous embodiment of the method according to the invention, schematically indicated in Fig. 8, the fluid transfer device includes at least one protective cap P which is removed before creating the fluid passage. If necessary, several protective caps, hoods, seals, or films can be provided on different portions of the fluid transfer device and the drug bottle according to the invention, and also on the injection port of the infusion system. This embodiment ensures that those

surfaces of the fluid transfer system which will be in contact with the infusion fluid and the supplied drug can be kept in a sterile condition.

As used herein, the expression "drug bottle" refers to any container which is leakage-proof and otherwise suitable for the purpose in question. Preferably, the "drug bottle" utilised in the assembly according to the invention has only one opening which is sealed by a closure or cap, and preferably is made of a solid, rigid and inflexible material, such as glass.

In the foregoing description, the present invention has been described in connection with a few specific embodiments and with reference to the attached drawings. However, the present invention is by no means strictly confined to these embodiments or to what is shown in the drawings, but the scope of the invention is defined in the following claims.

Accordingly, as illustrated in Figs. 2-3 and 5, the fluid transfer device according to the invention advantageously can be provided with a safety latch S which controls the telescopic action of the first 105; 205 and second 107; 207 members.

Claims

1. A fluid transfer device for use in an infusion system,
said fluid transfer device (100; 200) exhibiting a first end (101; 201), a second end (102; 202) opposite to said first end, said second end (102; 202) being designed and arranged for coupling to an injection port (103; 203) of said infusion system (104; 204), said fluid transfer device (100; 200) including at least a first member (105; 205), a hollow needle (106; 206) attached to said first member, a second member (107; 207) which is telescopically displaceable in relation to said first member (105; 205) in a way allowing said hollow needle (106; 206) to penetrate a flexible barrier member (108; 208) sealing said injection port (103; 203) in order to create a fluid passage from said first end (101; 201) via said injection port (103; 203) into said infusion system (104; 204),
characterised in that the first end (101; 201) exhibits a connecting portion (109; 209; 309; 409) for attachment to a drug bottle (110; 210) containing a fixed dose (D) of a medical substance, and that said second end (102; 202) exhibits a flexible membrane (111; 211) intended to be pressed against said flexible barrier member (108; 208) of said injection port (103; 204) with a pressure sufficient in order to create a double-membrane sealing (108, 111; 108, 211; 208, 211) around said hollow needle (106; 206) when creating said fluid passage into said infusion system (104; 204).

2. A fluid transfer device according to claim 1,
characterised in that the flexible membrane (111; 211) is made of a polymer material exhibiting a yield point when subjected to said pressure, and that said second end (102; 202) is designed and arranged for interacting with said injection port (103) in order to increase said pressure above said yield point.

3. A fluid transfer device according to claim 1,
characterised in that the second end (102; 202) is designed and arranged for creating said double-membrane sealing (108, 111; 108, 211) when said injection port (103) is provided on a flexible infusion bag (112) of said infusion system (104).

4. A fluid transfer device according to claim 1, characterised in that the second end is designed and arranged for creating said double-membrane sealing (208, 211) when said injection port is provided on an infusion fluid line of said infusion system or is connected to a spike device (SP) exhibiting said flexible barrier member (208).

5. A fluid transfer device according to claim 1, characterised in that the second end (102; 202) is designed and arranged for creating a double-membrane bayonet coupling with said injection port (103).

6. A fluid transfer device according to claim 1, characterised in that the connecting portion (109; 309) exhibits at least one locking member (113; 313) for grasping a bottle neck (114) of said drug bottle (110) in order to create a permanent attachment, and that said connecting portion (109; 309) further exhibits a hollow piercing member (115) for penetrating a bottle cap (116) of said drug bottle (110) in order to extend said fluid passage into said drug bottle.

7. A fluid transfer device according to claim 1, characterised in that the connecting portion (109) exhibits a hollow piercing member (115) for penetrating a bottle cap (116) of said drug bottle (110) in order to extend said fluid passage into said drug bottle, and that neighbouring ends of said hollow piercing member (115) and said hollow needle (106) are designed and arranged in a way allowing fluid communication through said hollow piercing member (115) into said hollow needle (106).

8. A fluid transfer device according to claim 1, characterised in that the connecting portion exhibits a hollow piercing member for penetrating a bottle cap of said drug bottle in order to extend said fluid passage into said drug bottle, and that said hollow piercing member is constituted of a sharpened end of said hollow needle being exposed at said first end of said fluid transfer device.

9. A fluid transfer device according to claim 1, characterised in that the connecting portion (209) exhibits a first coupling member (213) for engaging a second coupling member (217) provided on a bottle

cap (216) of said drug bottle (210) in order to create said attachment by means of a Luer-lock coupling.

10. A fluid transfer device according to claim 1, characterised in that the connecting portion (209) exhibits a first coupling member (213) for attachment to a second coupling member (217) provided on a bottle cap (216) of said drug bottle (210), wherein a fluid barrier member (218) is provided in a duct (219) extending between an interior (D) of said drug bottle (210) and said second coupling member (217) and said fluid barrier member (218) can be ruptured by means of an external force in order to extend said fluid passage into said drug bottle (210).

11. A fluid transfer device according to claim 1, characterised in that the connecting portion (209) exhibits a first coupling member (213) for attachment to a second coupling member (217) which is permanently attached to said drug bottle (210) at least by means of an annular capsule member (220).

12. A fluid transfer device according to claim 1, characterised in that the connecting portion exhibits a female Luer-lock connector (221) for attachment to a male Luer-lock connector (222) provided on said drug bottle (210).

13. A fluid transfer device according to claim 1, characterised in that the connecting portion exhibits a male Luer-lock connector for attachment to a female Luer-lock connector provided on said drug bottle.

14. A fluid transfer device according to claim 1, characterised in that the connecting portion is a separate component (109) which has been attached to said first member (105) before permanent attachment to said drug bottle (110).

15. A fluid transfer device according to claim 1, characterised in that the connecting portion is an integrated part (209) of the first member (205).

16. A fluid transfer device according to claim 1, characterised in that the connecting portion is a separate component (309) which exhibits a Luer-lock connector (323) for attachment to said first member (205) by means of a Luer-lock coupling (221, 323).

17. A fluid transfer device according to claim 1, characterised in that the connecting portion is a separate component (409) which exhibits:
- a Luer-lock connector (423) for attachment to said first member (205) by means of a Luer-lock coupling (221, 423);
- at least one locking member (413) for grasping a bottle neck (114) of said drug bottle (110) in order to create a permanent attachment; and
- a hollow piercing member (415) for penetrating a bottle cap (116) of said drug bottle (110) in order to extend said fluid passage into said drug bottle.

18. A drug bottle for use in an infusion system, characterised in that the drug bottle (110; 210) contains a fixed dose (D) of a medical substance, and that said drug bottle (110; 210) is intended for attachment to a fluid transfer device (100; 200) according to claim 1.

19. A drug bottle according to claim 18, characterised in that the drug bottle (110) exhibits a bottle neck (114) intended to be grasped by at least one locking member (113) of said connecting portion (109) in order to create a permanent attachment.

20. A drug bottle according to claim 18, characterised in that the drug bottle (110) exhibits a bottle cap (116) intended to be pierced by a piercing member (115; 315) being part of said fluid transfer device (100).

21. A drug bottle according to claim 18, characterised in that the drug bottle (210) is sealed by a bottle cap (216) exhibiting a second coupling member (217) intended to be attached to a first coupling member (213) of said connecting portion (209).

22. A drug bottle according to claim 18,
characterised in that that the drug bottle (210) is sealed by a bottle cap (216) exhibiting a second coupling member (217), and that a fluid barrier member (218) is provided in a duct (219) extending between an interior (D) of said drug bottle (210) and said second coupling member (214), and said fluid barrier member (218) can be ruptured by means of an external force in order to open said duct (219).

23. A drug bottle according to claim 18,
characterised in that that the drug bottle (210) is sealed by a bottle cap (216) exhibiting a second coupling member (217) intended to be attached to a first coupling member (213) of said connecting portion (209), wherein said second coupling member (217) is permanently attached to said drug bottle (210) at least partly by means of an annular capsule member (220).

24. A drug bottle according to claim 18,
characterised in that the drug bottle (210) is sealed by a bottle cap (216) exhibiting a male Luer-lock connector (222) intended to be attached to a female Luer-lock connector (221) of said connecting portion (209).

25. A drug bottle according to claim 18,
characterised in that the drug bottle is sealed by a bottle cap exhibiting a female Luer-lock connector intended to be attached to a male Luer-lock connector of said connecting portion.

26. A method for fluid transfer in an infusion system,
said method including to use a fluid transfer device (100; 200) to inject a medical substance into said infusion system (104) via an injection port (103) sealed by a flexible barrier member (108), said fluid transfer device including at least a first member (105; 205), a hollow needle (106; 206) attached to said first member, and a second member (107; 207) which is telescopically displaceable in relation to said first member (105; 205),
characterised in that the method includes:
- to provide said fluid transfer device (100; 200) having a first end (101; 201), and a second, opposite end (102; 202) exhibiting a flexible membrane (111; 211);
- to provide a drug bottle (110; 210) containing a fixed dose (D) of said medical substance;

- to attach said first end (101; 201) to said drug bottle (110; 210);
- to couple said second end (101; 201) to said injection port (103) while pressing said flexible membrane (111; 211) against said flexible barrier member (108) with a pressure sufficient for creating a double-membrane sealing (108, 111; 108, 211);
- to create a fluid passage from said first end (101; 201) to said infusion system by means of telescopically displacing said first end (101; 201) in a direction towards said second end (102; 202) in order to get said hollow needle (106; 206) to penetrate said flexible membrane (111; 211) and said flexible barrier member (108) while being surrounded by said double-membrane sealing (108, 111; 108, 211); and
- to transfer said fixed dose (D) from said drug bottle (110; 210) into said infusion system (104) by means of creating and subsequently releasing a positive pressure inside said drug bottle (110; 210).

27. A method for fluid transfer according to claim 26,
characterised in that the method includes to increase said pressure above a yield point of a polymer material constituting said flexible membrane (111; 211).

28. A method for fluid transfer according to claim 26,
characterised in that said injection port (103) is provided on a flexible infusion bag (112) of said infusion system (104).

29. A method for fluid transfer according to claim 26,
characterised in that said injection port is provided on an infusion fluid line of said infusion system.

30. A method for fluid transfer according to claim 26,
characterised in that the second end (102; 202) creates a double-membrane bayonet coupling with said injection port (103).

31. A method for fluid transfer according to claim 26,
characterised in that the method further includes:
- to penetrate a bottle cap (116) of said drug bottle (110) by means of a hollow piercing member (115; 315) in order to extend said fluid passage into said drug bottle; and
- to grasp a bottle neck (114) of said drug bottle (110) by means of at least one locking member (113) of said fluid transfer device (100) in order to create a permanent attachment.

32. A method for fluid transfer according to claim 26, characterised in that the attachment is created by means of a Luer-lock coupling (221; 222).

33. A method for fluid transfer according to claim 26, characterised in that a fluid barrier member (218) blocking a duct (219) extending through said bottle cap (216) is ruptured by means of an external force when extending said fluid passage into said drug bottle (210).

34. A method for fluid transfer according to claim 26, characterised in that a clamping member (C) is utilised for applying an external pressure on a duct (419) extending through said bottle cap in order to block said fluid passage into said drug bottle.

35. A method for fluid transfer according to claim 26, characterised in that the flexible membrane (211) of said second end is pressed against a flexible barrier member (208) of a spike device (SP) connected to said infusion system (204) before transferring said fixed dose from said drug bottle (210) into said infusion system (204).

36. A method for fluid transfer according to claim 26, characterised in that the fluid transfer device includes at least one protective cap (P) which is removed before creating said fluid passage.

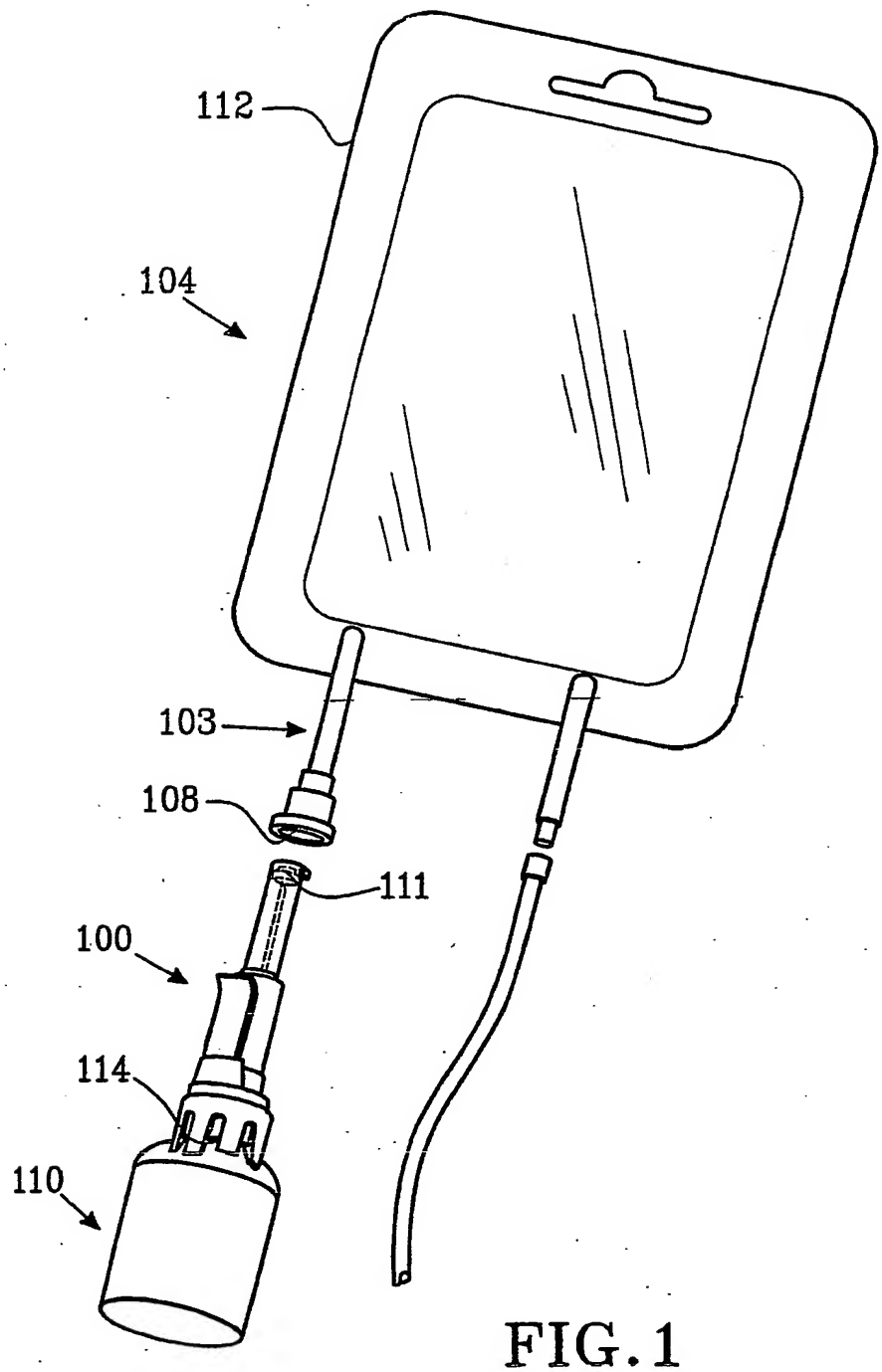

FIG. 1

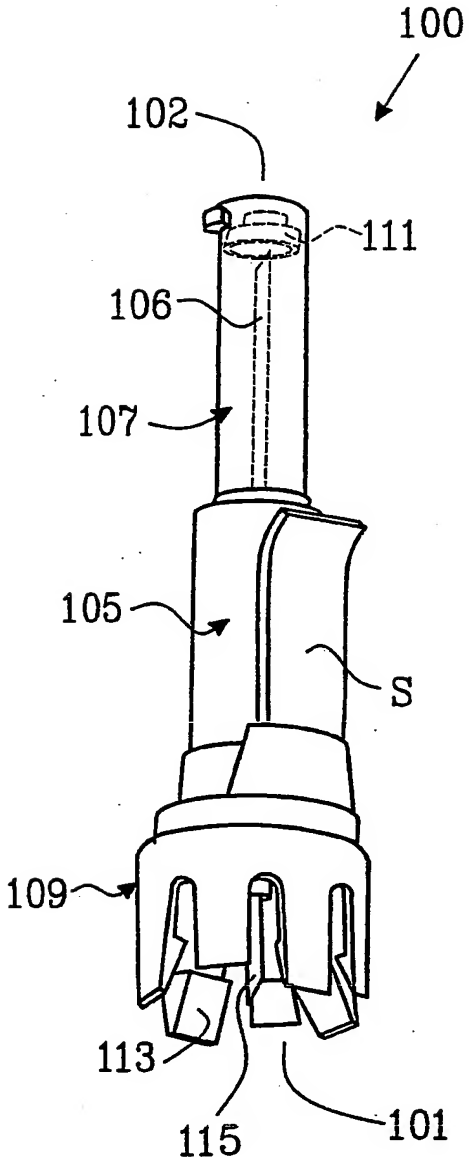
100
102
111
106
107
105
S
109
113
115
101

FIG.2

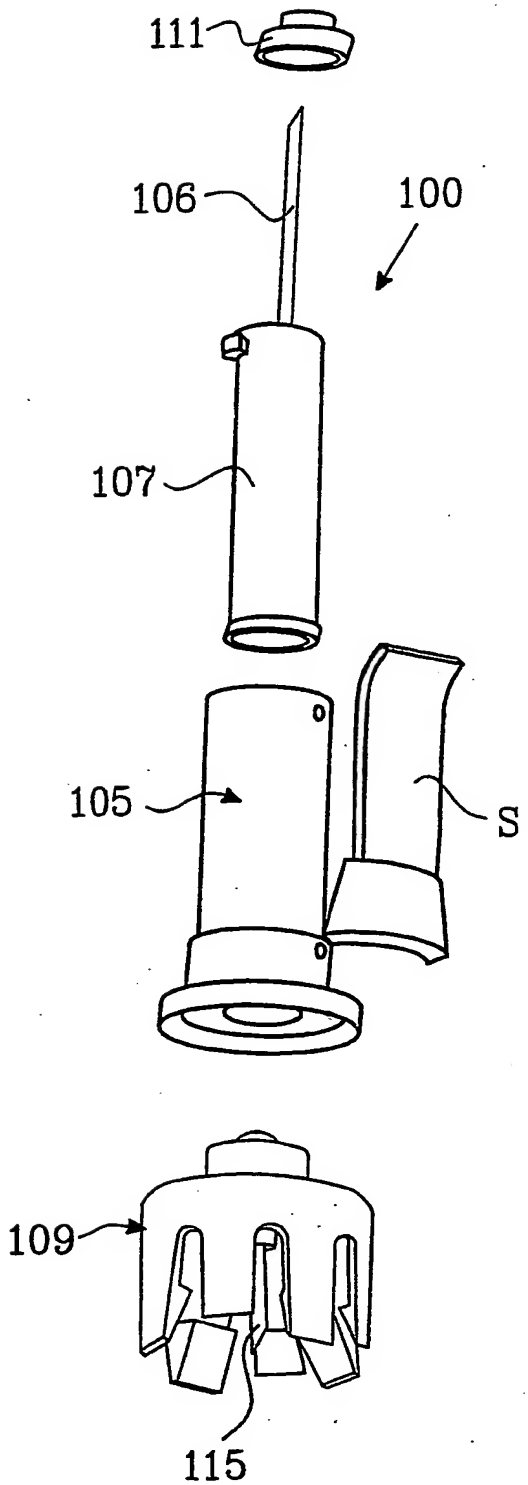
111
106
100
107
105
S
109
115

FIG.3

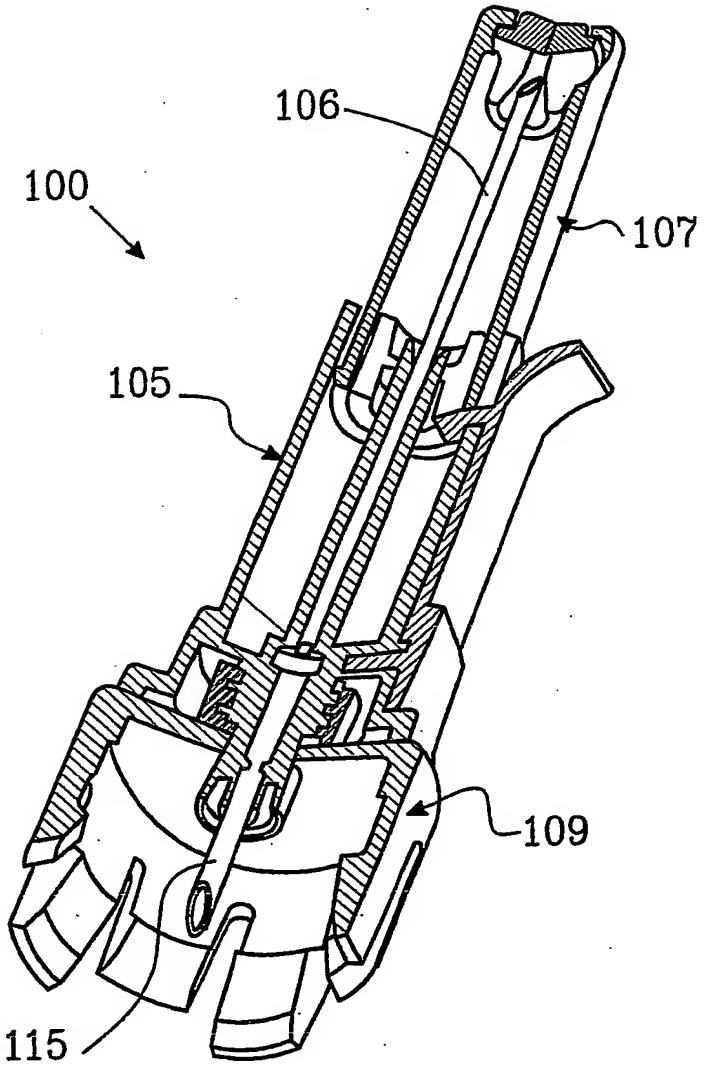

FIG.4

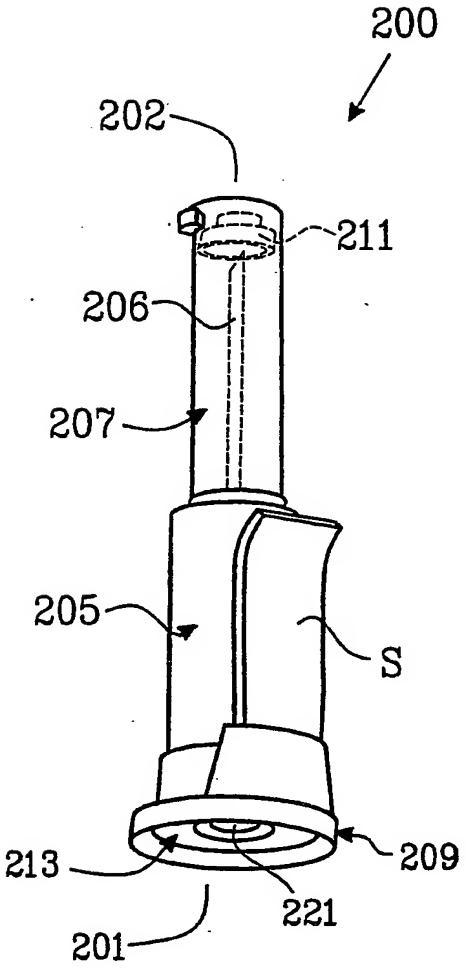

FIG.5

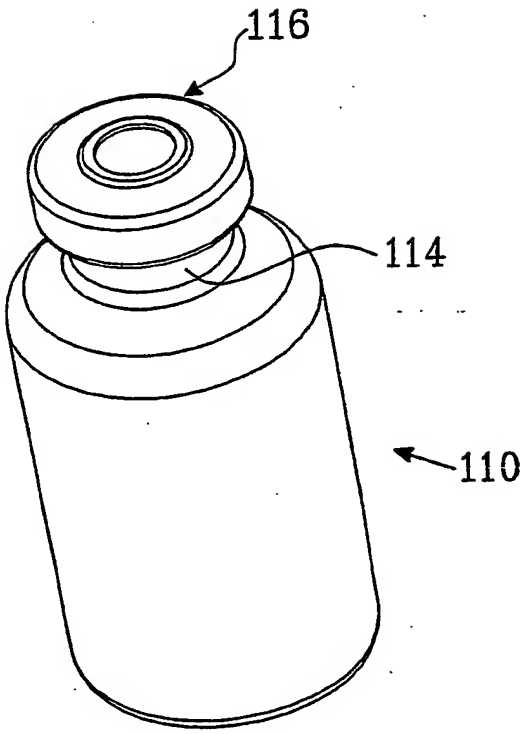

FIG.6

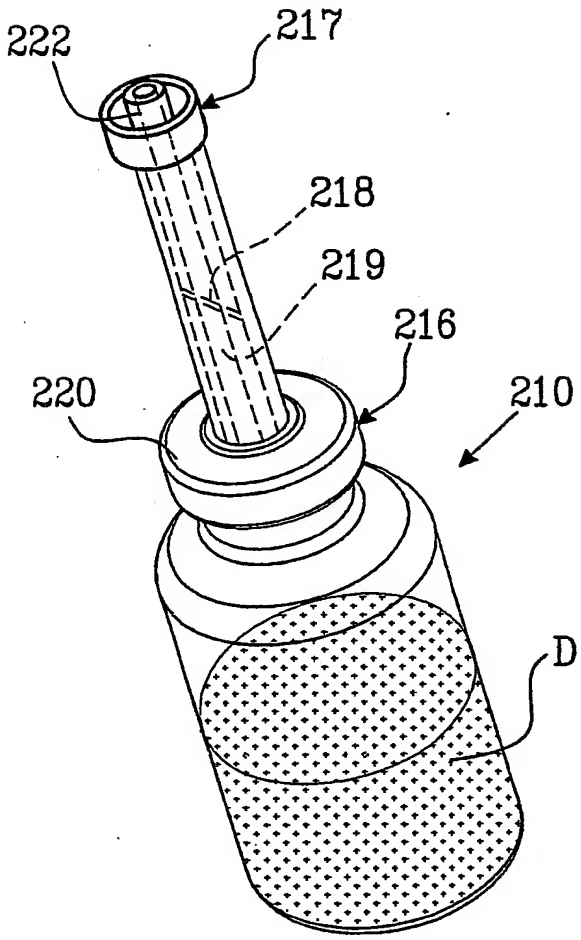

FIG.7

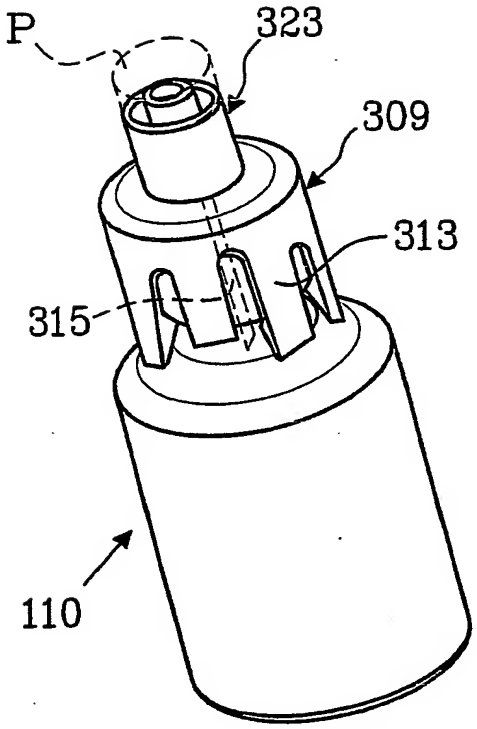

FIG.8

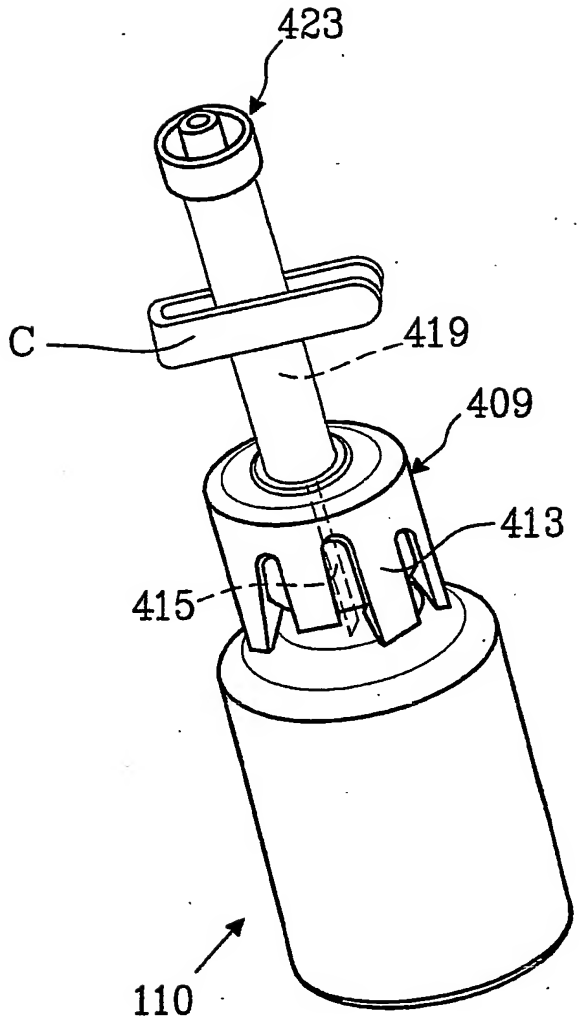

FIG.9

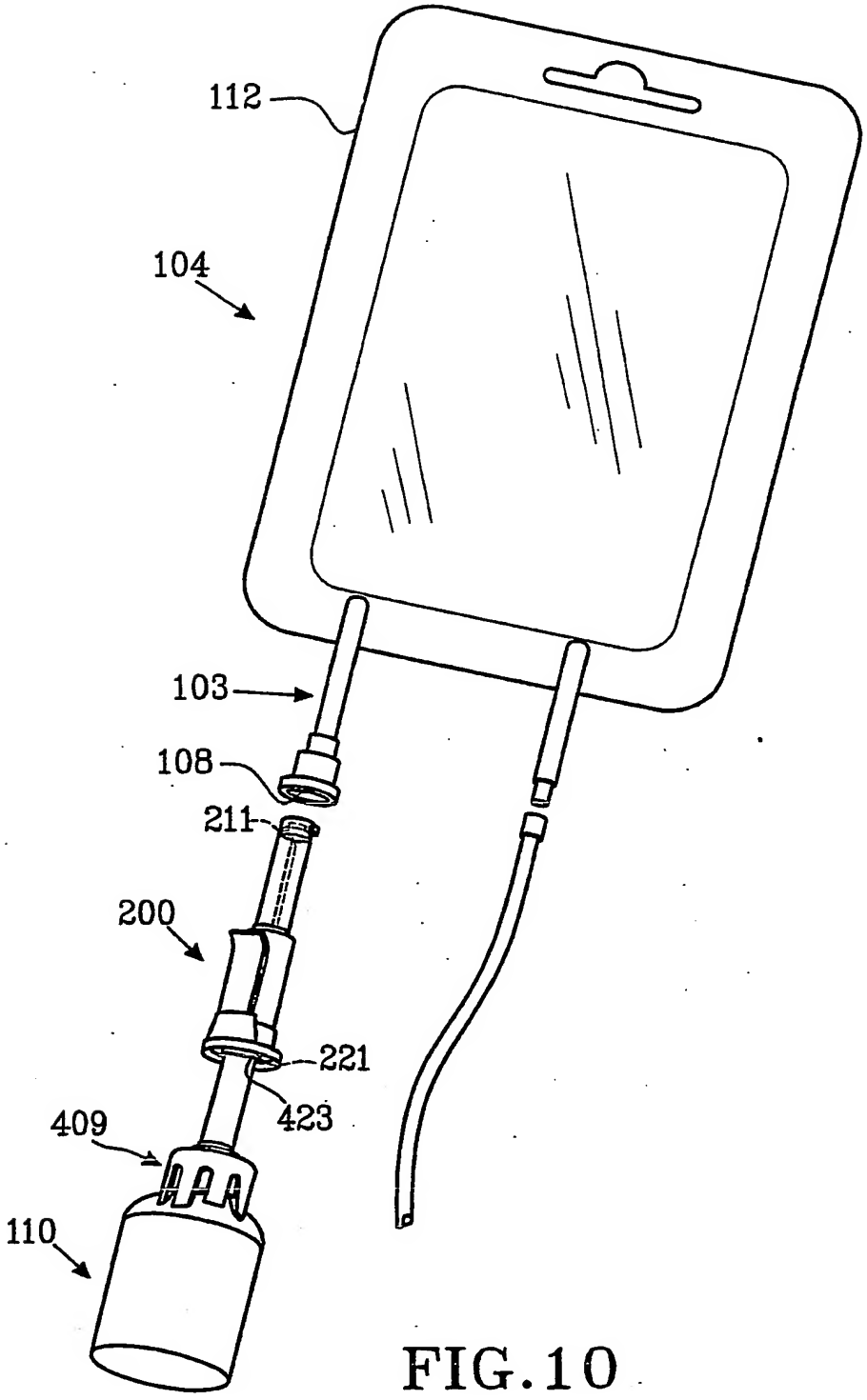

FIG.10

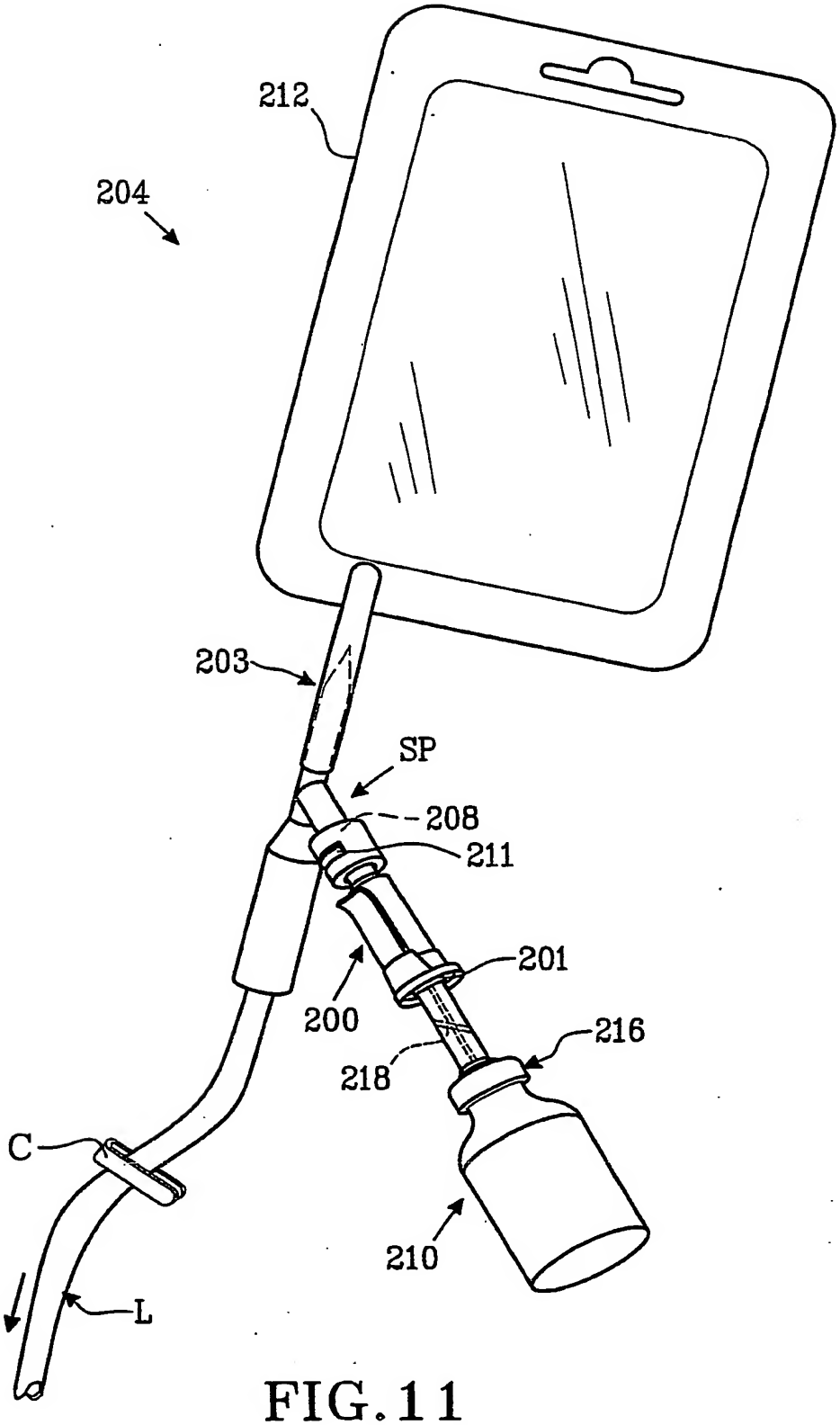

FIG.11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 03/00573

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 39/20, A61J 1/20, A61M 5/32 // A61J 1/10, A61M 39/28
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M, A61J, A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6113583 A (THOMAS A. FOWLES ET AL), 5 Sept 2000 (05.09.00), abstract, see the whole document, particularly column 7, line 30 - column 13, line 38, figure 1-7	1-9,11-20, 22-31,34,35
Y		10,21,32,33
	--	
A	US 4564054 A (BENGT GUSTAVSSON), 14 January 1986 (14.01.86), see the whole document, particularly column 2, line 28 - column 4, line 39, column 5, line 5 - line 20, figure 1-7,10	1-9,11-20, 22-31,34,35
	--	
A	US 20010025671 A (JASON H. SAFABASH), 4 October 2001 (04.10.01), figures 1-23, abstract	1-9,11-20, 22-31,34,35
	--	

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 August 2003	18 -08- 2003
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Pär Moritz /OGU Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 03/00573

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	US 5766147 A (GREGORY E. SANCOFF ET AL), 16 June 1998 (16.06.98), column 7, line 66 - column 8, line 19, figures 1-22, abstract	1-9,11-20, 22-31,33-35
Y		10,21,32
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A	US 5385547 A (JOSEPH WONG ET AL), 31 January 1995 (31.01.95), column 7, line 30 - line 44; column 10, line 55 - line 61, figures 3,4,10-12	1-32,34,35
Y		33
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PA	WO 02064077 A1 (FUKAI KOGYO KABUSHIKI KAISHA), 22 August 2002 (22.08.02), figures 7A,7F, abstract	1,2,25,26
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Y	US 5817083 A (SHEMESH, E. ET AL), 6 October 1998 (06.10.98), column 1, line 29 - column 2, line 13; column 3, line 1 - column 4, line 27, figures 1-5, claims 1-11	10,21,32,33
A		1-9,11-20, 22-31,34,35
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A	US 4997083 A (LORETTI, M. ET AL), 5 March 1991 (05.03.91), column 2, line 43 - line 52, figures 1, 2, abstract	10,21,32
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A	EP 0803267 A2 (B.BRAUN MELSUNGEN AG), 29 October 1997 (29.10.97), figures 1,2, abstract	10,21,32
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 03/00573

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. A fluid transfer device and a method using double membrane sealings. Claims 1-9, 11-20, 22-31, 34, 35.

2. A fluid transfer device having a breakable fluid barrier. Claims 10, 21, 32.

3. A method for fluid transfer using a clamp. Claim 33

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

26/07/03

International application No.
PCT/SE 03/00573

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26/07/03

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Information on patent family members

26/07/03

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PCT/SE 03/00573

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